REMARKS

Reconsideration of the subject application is respectfully requested.

Claims 1, 3-15, and 32-34 are pending in the present application. Claims 1, 7-8, 11, 15, and 32 are being amended. Claim 34 is being cancelled. Claim 35-37 are being added.

Independent claim 1 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,540,733 to Testerman et al. ("Testerman") in view of U.S. Patent No. 6,251,126 to Ottenhoff et al. ("Ottenhoff"). Claims 3-6 and 13 depend from claim 1 and stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Testerman in view of Ottenhoff and U.S. Publication No. 2002/0049479 to Pitts ("Pitts"). Claim 14, also dependent on claim 1, stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Testerman in view of Ottenhoff, Pitts, and U.S. Patent No. 6,904,320 to Park et al. ("Park"). Independent claim 7 and its dependent claims 8-12 and 32, as well as independent claim 15, stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Testerman in view of Ottenhoff, Pitts, and U.S. Patent No. 5,207,230 to Bowers ("Bowers"). Claim 33, dependent from claim 7, stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Testerman in view of Ottenhoff, Pitts, Bowers, and Park.

The present invention is directed to an implantable device and methods of treating sleep disordered breathing with the implantable device, wherein the device includes a detector to detect the presence of an obstruction by detecting changes in transthoracic impedance and a stimulator. The treatment is in the form of electrical or mechanical stimulation of afferent nerves. All of the methods of the present invention

detect aspects of a patient's real time condition and provide two different modes of stimulation, with the mode of stimulation based upon the patient's detected condition. In the methods, the likelihood of the patient being asleep is determined. In one embodiment, the likelihood is determined based on both time of day and sensing the patient's postural state. When the patient is determined to likely be asleep, stimulation is provided prophylactically so as to prevent airway collapse or to increase tone of upper airway muscles (Mode I). The detector of the device emits high frequency pulses, detects transthoracic impedance consequential to the pulses, and determines changes to the transthoracic impedance which are indicative of an obstruction. If an obstruction is determined to be present, the stimulation is increased (Mode II).

All claims stand rejected at least in part in view of the combination of Testerman and Ottenhoff. The Examiner relies on Testerman for disclosing a method of treating sleep disordered breathing comprising the steps of delivering treatment so as to prevent airway collapse if the patient is likely to be asleep, determining the presence of an obstruction in the patient's airway, and if an obstruction is present increasing the treatment until the obstruction is no longer present, wherein the treatment comprises applying stimulation to afferent nerves and the presence of an obstruction is determined by sensing a change in transthoracic impedance.

However, Testerman differs from the present invention in several ways. Testerman does not disclose use of time of day to determine the likelihood that the patient is asleep or any real time clock. Testerman also does not determine the likelihood that the patient is asleep by combined use of time and a postural sensor. Instead, Testerman assumes a sleep state once a predetermined time period expires

after the device is turned on. Once turned on, the device in Testerman imposes a delay before starting any stimulation, whereas the present invention does not impose a time delay. Further, Testerman does not disclose starting stimulation in response to determining the likelihood that patient is asleep but only after (1) the device is turned on, (2) a prescribed delay has taken place, and (3) the presence of an "event" has been determined. (see col. 15, ln. 9-16). In Testerman, all three of the aforementioned attributes are needed before stimulation may be provided. Testerman's method for determining the presence of an event is nothing like the change in thoracic impedance method of the present invention. Testerman determines the onset of an event by "moitoring changes in respiratory effort waveform" based upon "averag[ing] over successive respiratory cycles." (see Testerman Abstract). Also, because Testerman only discloses beginning stimulation upon determining the presence of an event, it does not disclose the bi-modal approach of the present invention or prophylactically providing stimulation. In other words, Testerman does not disclose or suggest bi-modal operation at all. Also, Testerman does not measure transthoracic impedance (or differences in transthoracic impedance) at all, let alone to determine the onset of an event, nor does Testerman transmit high frequency pulses so as to detect transthoracic impedance change.

The Examiner relies on Ottenhoff for determining the likelihood of a patient being asleep. However, Ottenhoff's disclosure differs from the present invention in several ways. The Ottenhoff device (1) does not include a real time clock, and (2) needs to be turned on manually or through EEG sensing (col. 5, ln. 16-20). In addition, Ottenhoff determines the likelihood that the patient is asleep, but not by the method of the present

invention in which the determination is based on both postural state and time of day. Also, Ottenhoff imposes a predetermined delay before commencing any stimulation. Ottenhoff does not deliver stimulation prophylactically but only after sensing respiratory effort of the patient. In other words, Ottenhoff does not disclose or suggest the bi-modal approach of the present invention.

In summary, even when combining Testerman with Ottenhoff, several attributes of the present invention are not disclosed or suggested, including an implantable device with all the elements of the device in the present invention, providing prophylactic stimulation, the bi-modal stimulation steps of the present invention, determining the presence of an obstruction using the approach of the present invention, and determining the likelihood of the patient being asleep or the mechanical stimulation aspects of the present invention. It is believed that claim 1 is in condition for allowance.

The Examiner relies on Testerman, Ottenhoff, and Pitts for the rejections of claims 3-13 and 32-33. Pitts' disclosure also differs from the present invention in several ways. The Pitts' device does not include a real time clock, a postural sensor, or a detector to detect changes in thoracic impedance. Pitts also does not provide bi-modal stimulation as described in the present invention. In Pitts, the only stimulation is a low level stimulation and Pitts does not describe any increase or change in stimulation. Further, Pitts does not disclose how the likelihood of the patient being asleep is determined other than "[t]he device(s) is turned on as the patient goes to bed." (paragraph 30). Pitts does not disclose a real time clock. The Pitts reference to "selected time of day" is not a disclosure or suggestion to use a real time clock and Pitts does not disclose or suggest that a clock and postural sensor are housed within an

implantable device and used together for detecting a patient's sleep state. Without a real time clock or position sensor, the method of Pitts cannot be the method of the present invention. Finally, Pitts does not even disclose determining the presence of an obstruction.

Even when combining Testerman, Ottenhoff, and Pitts, several attributes of the present invention are not disclosed or suggested, including an implantable device with all the elements of the present invention's device, the bi-modal stimulation of the present invention, determining the presence of an obstruction using the approach of the present invention, and determining the patient's sleep state as in the present invention or the mechanical stimulation aspects of the present invention. It is believed that claims 3-6 and 13 are in condition for allowance.

The Examiner relies on Testerman, Ottenhoff, Pitts, and Park for the rejection of claim 14. Park does not disclose or suggest elements claimed in the present invention either. Park is directed to sleep apnea therapy using dynamic overdrive pacing within a cardiac stimulator and a physiological sensor. The present invention is directed to stimulating afferent nerves, not the heart. Park does not determine the likelihood that the patient is asleep based upon the time of day. Park also does not disclose detecting changes to or determining the presence of an obstruction based upon transthoracic impedance. Park does not increase treatment based on changes to transthoracic impedance. In Park, the detection of sleep apnea is limited to sensing cardiac electrical phenomena (col. 4, ln. 56-57) or to a physiological sensor to sense physical motion or metabolic demand (col. 5, ln. 55-60). Park's method is distinct from determining an obstruction by detecting transthoracic impedance changes.

The Examiner relies upon Bowers (col. 3, ln. 20-23) for the step of mechanical stimulation of nerves to increase muscle tone to reject claims 7-12 and 32-33. Bowers is directed to a sensor with a transducer film which attaches to a body portion to record mechanical forces or potentially to provide stimulation. However, Bowers does not disclose nor even discuss nerve stimulation to increase muscle tone, nor does Bowers disclose or suggest numerous elements of the claims of the present invention. Bowers does not determine the sleep state of the patient in any way. Bowers does not disclose bi-modal use at all and, in particular, does not disclose bi-model use as detailed in the claims of the present invention. Bowers does not determine the onset of an obstruction. More broadly, Bowers does not disclose or suggest the use of a sensor or any other device to treat sleep disorders. Further, Bowers does not suggest sensing changes in transthoracic impedance. In short, Bowers discloses a piezo-mechanical device but does not disclose its use in an implantable device such as in the present invention nor does it disclose the methods of the present invention.

In summary, even when combining Testerman, Ottenhoff, Pitts, Park, and Bowers, in any combination, several features of the present invention which are not disclosed or suggested include an implantable device with all the claimed elements, including bi-modal stimulation, determining the presence of an obstruction, and determining the likelihood that the patient is asleep. As a result, it is believed that claim 1 is not obvious in view of Testerman and Ottenhoff, claims 3-6 and 13 are not obvious in view of Testerman, Ottenhoff, and Pitts, claim 14 is not obvious in view of Testerman, Ottenhoff, Pitts, and Park, claims 7-12, 15, and 32 are not obvious in view of Testerman, Ottenhoff, Pitts, and Bowers, and claim 33 is not obvious in view of

Testerman, Ottenhoff, Pitts, Bowers, and Park. It is believed that all of the aforementioned claims are in condition for allowance.

The allowance of claims 1, 3-15, 32-33, and 35-37 and the early passage to issue of the application are respectfully requested.

Respectfully submitted,

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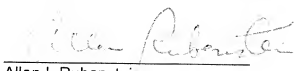

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